



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SUBJECT: Product Chemistry Review of Refined Pyrethrum Concentrate (EPA ID#36426-R) OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

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6-25-92

Applicant: Office du Pyrethre au Rwanda (OPYRWA)

EPA ID#: 36426-R

Pesticide Chemical Code (PCC): 069001

CAS No: 121-21-1

Chemical Name: Pyrethrins

Product Name: Refined Pyrethrum Concentrate

Use: Insecticide

INTRODUCTION:

The Fairfield American Corporation, Agent for Office du Pyrethre au Rwanda (OPYRWA), has requested that the Agency proceed with reviews of the product applications for Crude Pyrethrum Extract (EPA ID# 36426-G) and Refined Pyrethrum Concentrate (EPA ID# 36426-R). (See letter of 7/24/91, Jan Brill, Regulatory Manager.) Additionally, the PM Team No. 10 has requested reviews of the product chemistry data in order to determine if : (1) the Crude Pyrethrum Extract is similar or identical to a registered source; (2) available product chemistry data meets the requirements for manufacturing processes and analytical methods. The PM Team No. 10 has also requested a review of the product chemistry data for the product Refined Pyrethrum Concentrate.

The product Crude Pyrethrum Extract (EPA ID#36426-G) is refined to produce the product Refined Pyrethrum Concentrate (EPA ID# 36426-R). The Refined Pyrethrum Concentrate is then used as a Manufacturing-Use Product (MP) to produce End-Use Products.

CONCLUSIONS ON THE CRUDE PYRETHRIN EXTRACT (EPA ID# 36426-G)

Reviews and comparisons of the unregistered crude pyrethrin extract product with registered crude pyrethrin extract products show that the unregistered Crude Pyrethrin Extract product (EPA ID# 36426-G) is substantially similar to the registered pyrethrin product (EPA Reg. No. 1021-1067).

The product chemistry data submitted for the Crude Pyrethrin Extract (MRID No. 414746-01) meet the requirements of 40 CFR 158.150 - 158.190.

The Crude Pyrethrin Extract (EPA ID# 36426-G) is acceptable for registration based on the product chemistry data.

DISCUSSION OF PRODUCT CHEMISTRY DATA FOR THE PRODUCT REFINED PYRETHRUM CONCENTRATE (EPA ID# 36426-R)

The product chemistry data for the Refined Pyrethrum Concentrate (EPA ID# 36426-R; MRID Nos. 413112-01, 413112-02, 413112-03) has been reviewed, and the applicant has been informed of questions raised on the data (See letter of January 24, 1991, Richard F. Mountfort, PM 10). The questions raised are discussed below.

"A. Provide preliminary analyses of five or more representative samples to identify all impurities present at > 0.1%...."

The applicant indicated in the data package (MRID No. 413112-02, 62-1: Preliminary Analysis) that since the product was not produced by an integrated formulation system, the preliminary analysis was not required.

However, the Agency response indicated that a preliminary analysis was required (see quote above). The present submission consists of registration requests for the active ingredient (ai) source product (Crude Pyrethrum Extract) and the Manufacturing-Use Product (Refined Pyrethrum Concentrate). PCRS/RSB has concluded that the Crude Pyrethrum Extract product is similar to an already registered product and is acceptable for registration. This conclusion would eliminate the need for preliminary analysis for the Refined Pyrethrum Concentrate. This resolves the question raised on preliminary analysis.

"B. Provide an explanation as to how all certified limits were established ... You may propose different certified limits, provided an adequate explanation is submitted. In addition, you must submit an updated Confidential Statement of Formula on EPA Form 8570-4 (Rev. 2-85). The new CSF should identify the specific active principles and solvents contained in the product; ..."

The applicant has provided information which adequately demonstrates and explains the establishment of certified limits for pyrethrins (MRID No. 413112-01). However, the requested CSF which should contain the identity of the active ingredients and the chemical identity of the solvents present in the product has not been submitted. The revised CSF is needed for informational purposes and should be submitted.

"C. Provide validation data or statements regarding precision and accuracy for the analytical method used to determine the active ingredients...."

The analytical methods used to determine the active ingredients as well as all components in the product is provided (MRID No. 413112-01). Although the accuracy and precision has not been specifically provided, the data (assay values; means) are provided which may be used to determine these values. Therefore, this question is considered resolved. No additional data are needed.

SUMMARY

The questions raised above concerning the product chemistry data requirements for the pyrethrin products have been resolved, and no additional data are needed. However, a revised CSF is needed which contains the chemical identity of the solvent used in addition to the identities of the other components of the product.